

117TH CONGRESS
1ST SESSION

S. _____

To codify the successes of rapid development of safe vaccines through Operation Warp Speed, for the next administration to use as a guide in the event of another pandemic.

IN THE SENATE OF THE UNITED STATES

Mr. COTTON introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To codify the successes of rapid development of safe vaccines through Operation Warp Speed, for the next administration to use as a guide in the event of another pandemic.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Operation Warp Speed
5 Act of 2021”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

1 (1) COVID–19 has infected more than
2 32,000,000 people in the United States and taken
3 the lives of more than 550,000.

4 (2) The Trump Administration’s creation of
5 Operation Warp Speed, on May 15, 2020, and the
6 development of 3 COVID–19 vaccines, in less than
7 a year, was the greatest success in getting the
8 COVID–19 pandemic under control, and one of the
9 greatest public health programs in history.

10 (3) As a result of the Trump Administration’s
11 partnership with the private sector, more than
12 150,000,000 doses of authorized vaccines have been
13 administered in the United States.

14 (4) The unprecedented rapid deployment of
15 COVID–19 vaccines and therapeutics, thanks to the
16 public-private partnership of Operation Warp Speed,
17 has helped the United States combat the spread of
18 COVID–19, protect at-risk populations, save millions
19 of lives, and return to normal life.

20 **SEC. 3. CODIFYING SUCCESSES.**

21 (a) ADDRESSING THE STRATEGIC NATIONAL STOCK-
22 PILE.—

23 (1) ANNUAL THREAT-BASED REVIEW.—In con-
24 ducting the annual threat-based review with respect
25 to the Strategic National Stockpile under section

1 319F–2(a)(2)(A) of the Public Health Service Act
2 (42 U.S.C. 247d–6b(a)(2)(A)), the Secretary of
3 Health and Human Services (referred to in this sec-
4 tion as the “Secretary”) shall ensure that such re-
5 view considers, and the report to Congress includes,
6 information about the supply levels in such stockpile
7 and any materials that may be missing. The review
8 described in the previous sentence shall include a
9 supply chain assessment of materials in the Stra-
10 tegic National Stockpile that considers whether the
11 United States could procure such materials in the
12 event of a pandemic that limits trade and access to
13 international supply chains.

14 (2) PROCURING SUPPLIES FOR THE SNS.—In
15 procuring supplies for the Strategic National Stock-
16 pile under section 319F–2(a) of the Public Health
17 Service Act (42 U.S.C. 247d–6b(a)), the Secretary
18 shall—

19 (A) give priority to manufacturers of such
20 supplies, including vaccines, that are manufac-
21 tured by companies located in the United
22 States;

23 (B) in the case that no domestic manufac-
24 turer is available for certain supplies, including
25 vaccines, assess ways to ramp up domestic

1 manufacturing of such supplies, including vac-
2 cines; and

3 (C) in the case that no domestic manufac-
4 turer is available for certain supplies, including
5 vaccines, and it is determined that domestic
6 manufacturing cannot be ramped up in an ap-
7 propriate amount of time, give priority to com-
8 panies that are located in countries other than
9 the People’s Republic of China.

10 (b) INCREASING SPEED FOR SAFE EUA.—Section
11 564 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 360bbb–3) is amended—

13 (1) in subsection (c)—

14 (A) in the matter preceding paragraph
15 (1)—

16 (i) by inserting “the Commissioner of
17 Food and Drugs,” before “the Assistant
18 Secretary for”; and

19 (ii) by striking “the Secretary con-
20 cludes” and inserting “not fewer than 3 of
21 such Commissioner, such Assistant Sec-
22 retary, and such Directors, vote in favor of
23 such authorization after concluding”;

24 (B) in paragraph (4), by striking “; and”
25 and inserting a semicolon;

1 (C) by redesignating paragraph (5) as
2 paragraph (6); and

3 (D) by inserting after paragraph (4) the
4 following:

5 “(5) that the product complies with standards
6 for clinical trials established by the Secretary, in
7 consultation with such Commissioner, such Assistant
8 Secretary, and such Directors; and”.

9 (2) by adding at the end the following:

10 “(n) CONSIDERATION OF DATA.—The Secretary, and
11 the heads of agencies described in subsection (c), shall
12 consider the data submitted with respect to a product for
13 which authorization is being sought under this section, on
14 a rolling basis, as such data becomes available to such Sec-
15 retary and heads of agencies.”.

16 (c) GAPS IN CLINICAL TRIALS.—The Director of the
17 National Institutes of Health shall assess any geographical
18 gaps in clinical trial sites for drugs or biological products
19 and shall develop a plan for increasing the number of such
20 sites across broad geographic areas.

21 (d) REQUIRING ASPR TO IMPROVE MANUFACTURING
22 CAPABILITIES UNDER CONDITIONS OF PRESSURE.—

23 (1) VACCINE PRODUCTION.—The Secretary is
24 authorized to use amounts made available to the De-
25 partment of Health and Human Services for pur-

1 poses of producing vaccines in response to a public
2 health emergency prior to emergency use authoriza-
3 tion of such vaccine under section 564 of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C.
5 360bbb-3) or licensure of such vaccine under section
6 351 of the Public Health Service Act (42 U.S.C.
7 262).

8 (2) OPERATION WARP SPEED DIRECTOR.—Sec-
9 tion 2811 of the Public Health Service Act (42
10 U.S.C. 300hh-10) is amended by adding at the end
11 the following:

12 “(g) OPERATION WARP SPEED DIRECTOR.—There is
13 established within the Office of the Assistant Secretary for
14 Preparedness and Response an Office of Operation Warp
15 Speed, for purposes of responding to public health emer-
16 gencies by ensuring timely and sufficient development of
17 vaccines and other medical countermeasures (including
18 vaccines, therapeutics, and diagnostics), as well as domes-
19 tic manufacturing, through preparation in advance of any
20 such public health emergency. Such Office shall be headed
21 by a Director who has substantial relevant private sector
22 experience and is appointed by the President, by and with
23 the advice and consent of the Senate.”.